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DISCUSSION OF PRIOR ART

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Application Title: PROPHYLACTIC DEVICE INCLUDING A LINER BODY AND

METHOD OF USE Att'y Doc #: 0521-01

Relevant Patents Discovered

The most pertinent prior art is as follows:

US 5361779

US 5623945

US 5486322

US 5483697

US 5045341

US 2586674

US 5513654

US 2586674

The prior art shows the use of spandex or similar knitted material to increase the friction between a penis and a condom, for the purposes of preventing slippage of the condom with respect to the penis. For example:

The US **5361779** patent discloses a generally loose-fitting tubular sheath article, such as a condom, which has a closed distal end and an open proximal end which is bounded by a knitted material that bears compressively on the sheathed member to provide retention. The knitted material may be in the form of a band which is affixed to the sheath by everting (i.e., turning inside out) a portion of the sheath material at the proximal end over the knitted material and attaching the sheath material to itself, thereby creating a toroidal enclosure in which the knitted material is disposed. Constriction of the sheathed member is minimized by the knitted material which provides a large surface area for retentive contact.

FIG. 1 of the US5361779 patent is a perspective view of a generally tubular sheath article 1 comprising a main sheath portion 10 having an open proximal end 14 at its proximal portion 16 and a closed distal end 12. The main sheath portion 10 may suitably be formed of a polyurethane thin film material, being of a size appropriate to usage as a condom or prophylactic article, i.e., for closely overfitting a human penis.

FIG. 2 shows the sheathing article, having its constituent parts number correspondingly with respect to FIG. 1, with a knitted retention band 18 disposed on an exterior surface at

the proximal portion 16 of the condom, whereby a proximal skirt 20 is extended proximally from the part of the sheath circumscribed by the knitted retention ring 18.

The knitted retention ring 18 may for example be formed of a needle-knitted tubular material having a needles per course characteristic of from 50 to 100 needles per course, and formed of a yarn consisting of two ends of false-twist textured nylon and one end of spandex, wherein the spandex yarn may be S, Z wrapped with nylon.

The sheathing article 1 is shown in FIG. 3 as a finished article, wherein the skirt portion 20 of the main sheath is everted (i.e., turned inside out) over the knitted retention ring 18 and sealed, as by heat seal 22 to the main sheath, whereby the everted and overlapped portion 20 of the sheath forms a pocket or enclosure containing the knitted retention ring 18.

While this reference teaches the use of a textile material as an inner layer of a condom, the textile is used to grip the penis and prevent slippage. The present invention includes additional features and most particularly the inclusion of a lubricant that facilitates slippage of the penis with respect to the condom. While the addition of a lubricant to the exterior of a condom is well known, the addition of a lubricant to the inside of a condom having a textile material inner layer is not only not shown, but is contrary to the teachings of the prior art (which include the textile layer to increase grip).

The US5623954 patent describes a two layer prophylactic device taking the form of a male or female condom, or female diaphragm. The invention includes two latex layers bonded to one another along a spiral path which defines a corresponding spiral chamber between the latex layers. This spiral chamber extends between two compliant chambers at opposed ends of the device and is filled with a pharmacological fluid. Should one layer rupture during use, the pharmacological fluid will flow through the rupture and coat the adjacent sex organ.

Other examples of a similar construction are shown in US 5513654, and US 2586674 (two latex layers, with the internal layer providing a no-slip surface).

The US 5486322/US5483697 patents describe multilayer protective coverings such as a surgical gloves, finger cots, and condoms, and methods for making same. The protective coverings have two layers with a middle layer of sealing solution disposed between the two layers. The solution operates to fill punctures or tears in the two layers. The middle layer may include an evaporation inhibitor to inhibit evaporation of antimicrobial or sealing solutions in the middle layer. "In a preferred embodiment, the inner and outer layers are made of latex. Alternatively, the layers may comprise vinyl or neoprene. Latex provides adequate tear resistance for surgical procedures and allows for a good sense of feel for the wearer." (US5483697, col. 4, lines 1-5.)

The US **5045341** patent describes a covering such as a suit, glove, condom or sheath forming a chemical barrier against harmful agents. The covering is flexible, stretchable, and relatively thin, and includes at least one relatively thin chemical barrier that will

neutralize the harmful characteristics of the harmful agents. If an object cuts through the covering and into a person's skin or if a harmful agent tries to traverse through the covering, the chemical barrier will neutralize the harmful characteristics of the harmful agent so that the agent is neutralized either before reaching the person's skin, after reaching the person's skin, or both. Various methods of making the covering are also disclosed.

FIG. 7 of the US5045341 patent shows a covering comprising an outer layer 50 of latex, plastic or other suitable material, an intermediate layer 52, and an inner layer 54, which also may be

fashioned of latex, plastic or other material. The intermediate layer 52 may be formed of a material with a plurality of tiny voids or chambers, including microscopic chambers or pores, that encapsulate the chemical barrier.

FIG. 8 of the US5045341 patent shows another covering construction comprising an outer layer 56 similar to the outer layer 50 shown in FIG. 7, an intermediate layer 58, and an inner layer 60 similar to the inner layer 54 depicted in FIG. 7. The intermediate layer 58 may be formed of a variety of different materials. For example, the intermediate layer 58 may be formed of an absorbent material such as cellulose (e.g., paper), natural fiber (e.g., cotton) or synthetic fibers in either woven or unwoven condition. Also, a super absorbent material such as the materials used in baby diapers and in tampons may be used. If the chemical barrier is in fluid form, then preferably the chemical barrier substantially saturates the intermediate layer 58 and will not significantly flow in response to gravity or other forces. The intermediate layer 58 may also comprise a sponge-like material, which again can be saturated with chemical barrier in fluid form.

Additional references are listed in the enclosed form 1449, and these references disclosure features similar to the above-described references.

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